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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,997	01/16/2004	Michael Nyle Hershberger	P155	7917

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EXAMINER

SCHLENTZ, NATHAN W

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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03/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/758,997	Applicant(s) HERSHBERGER, MICHAEL NYLE	
	Examiner NATHAN W. SCHLIENTZ	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 8-14, 27-33 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 15-26 and 34-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/12/04, 8/10/04, 5/13/05, 10/24/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 9-14, 28-33 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 22 October 2007.

The examiner notes that Applicants elected multiple species, lufenuron, ivermectin and an antibody, for search and examination purposes. However, the examiner requested Applicants elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable (pg. 4, ll. 16-18 of the Restriction requirement mailed 20 September 2007). Therefore, the election of the first species lufenuron for the search and examination of claims 6, 7, 25 and 26 is conducted herein. As a result, claims 8 and 27 are withdrawn from further consideration as being drawn to a nonelected species.

Status of Claims

Claims 1-7, 15-26 and 34-38 are examined herein on the merits for patentability. No claim is allowed at this time.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 20-26 and 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by “essentially free of tomato flavor”. The term “essentially free of” is a term of degree that is not defined in the specification. One skilled in the art would be unable to determine what range of tomato flavor would be within the scope of the instant claims. Therefore, the scope of the instant claims is not clear.

2. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 recites the limitation "said first composition" in the 3rd line of the claim. There is insufficient antecedent basis for this limitation in the claim. It is believed by the examiner that Applicants intended to state “a first composition comprising a medicament, wherein *said first composition* is...” This interpretation would be consistent with instant claim 19 which is identical to claim 38 except the composition is essentially free of sugars instead of tomato flavor.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5 and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0025325 (Chu et al.).

Chu et al. disclose compositions for oral vaccination of healthy animals through drinking water or syrups comprising admixing a palatable flavorant with a vaccine formulation in order to promote self-administration of the vaccine formulation and/or to prevent rejection of the formulation when administered by an animal handler (Abstract). Chu et al. disclose an example wherein the lyophilized vaccine is resuspended in a flavored diluent, mixed with 5 liters milk solution containing non-fat dry milk, and then further diluted with 7 liters of water ([0102]). Also, Chu et al. disclose that flavorants for use in the vaccine formulations include fruit flavors preferred for horses, cats and dogs, meat flavors preferred for dogs and cats, and fish flavors preferred for cats ([0029]). Therefore, Chu et al. anticipate the instant claims drawn to a liquid composition comprising a medicament, flavorant and water, wherein the composition is essentially free of either sugars or tomato flavor.

With respect to the pH of the instantly claimed compositions being from about 3 to about 7, the pH of the Chu et al. formulations would inherently be from about 3 to about 7. The compositions are first diluted with milk, which is slightly acidic (i.e. pH of

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about 6.5 to about 6.7), then further diluted with water, which is neutral (i.e. pH of about 7). Therefore, the pH of the formulations of Chu et al. would inherently be within the instantly claimed pH range. The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-7, 15-26 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0058683 (Tinembart et al.) in view of Chu et al.

Applicant claims:

Applicants claim a liquid composition comprising lufenuron, a flavorant and water, wherein the composition is essentially free of sugars.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Tinembart et al. teach a veterinary preparation for fleas comprising lufenuron and nitenpyram, wherein oral administration of a liquid composition comprising lufenuron and nitenpyram effectively controlled flea infestation ([0057]-[0058]). Tinembart et al. also teach that because of its simple practicability, oral usage is one of the preferred subjects of the invention, especially the administration of tablets or suspensions, wherein additives are used to encourage willing consumption by the host animal, such as suitable odorous substances, flavorings and/or taste substances ([0061]-[0063]). Tinembart et al. teach that the lufenuron and nitenpyram are present from 0.1-95 wt.% and a liquid, physiologically acceptable carrier is present from 99.9-5 wt.% ([0078]). Tinembart et al. teach that the dosages may be carried in specially designed packs for administration by the veterinarian or keeper ([0075] and [0087]).

Furthermore, Tinembart et al. teach an emulsifier concentrate example comprising 20 wt.% active substances (i.e. lufenuron and nitenpyram), 20 wt.% emulsifier, and 60 wt.% solvent, and the composition is diluted with water to the desired concentration (Example 6). Also, Tinembart et al. teach drink additive examples comprising 15 wt.% of active ingredient, 10 wt.% of the active ingredient in diethylene glycol monoethylether, 10 wt.% in polyethylene glycol 300, and 5 wt.% in glycerol (Example 7).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Tinembart et al. do not explicitly teach the liquid preparation comprising lufenuron and nitenpyram wherein the composition is essentially free of sugars or tomato flavor. However, Chu et al. teach that flavorants for use in the oral vaccine formulations to be administered to animals through drinking water include fruit flavors preferred for horses, cats and dogs, meat flavors preferred for dogs and cats, and fish flavors preferred for cats ([0029]).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to prepare liquid formulations for oral administration of lufenuron and nitenpyram comprising flavorings and water, as taught by Tinembart et al., wherein the flavorings comprise fruit flavors preferred for horses, cats and dogs, meat flavors preferred for dogs and cats, and fish flavors preferred for cats, as reasonably taught by

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Chu et al. Also, one of ordinary skill in the art would have been motivated to package the compositions in specially designed packs, or kits, for the veterinarian or keeper to administer the predetermined dosage at predetermined intervals, as reasonably taught by Tinembart et al. With regard to the instantly claimed kits comprising a plurality of compartments, it would have been *prima facie* obvious for one of ordinary skill in the art to provide a kit comprising multiple compartments in order to have several dosages within one pack or kit, which need to be administered according to a dosage scheme, as taught by Tinembart et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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February 20, 2008